

Litigation arising from the use of soft-tissue fillers in the United States

To the Editor: With the increased use of soft-tissue fillers, there has been a concomitant rise in litigation asserting harm as a result of treatments. In 2013, nearly 1 million soft-tissue filler procedures were performed.^{1,2} We sought to examine a legal database for litigation and disciplinary actions involving soft-tissue fillers.

In July 2014, online public legal documents were searched using the national legal research service WestlawNext. We searched 3 database categories: cases; trial court orders, and administrative guidance and decisions. “Cases” contains opinions issued by state and federal trial, appellate, and supreme courts. “Trial court orders” contains decisions by state trial courts. “Administrative guidance and decisions” contains opinions from a variety of regulatory agencies outside of the judicial branch, including agencies that regulate physicians.

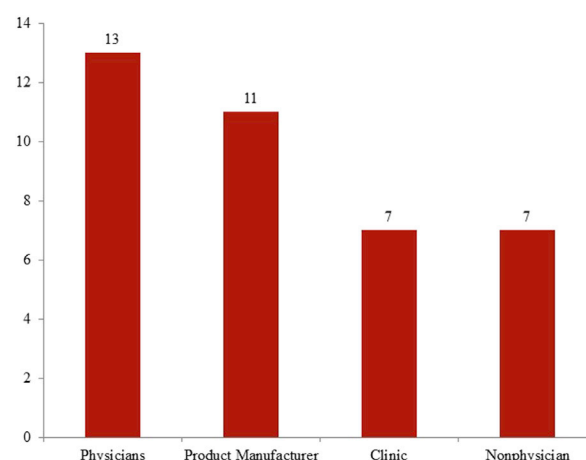


Fig 1. All defendants named in litigation related to soft-tissue filler injections. Many of the lawsuits named multiple defendants. Bar graph shows how physicians are the most commonly charged in litigation regardless of who performed the procedure.

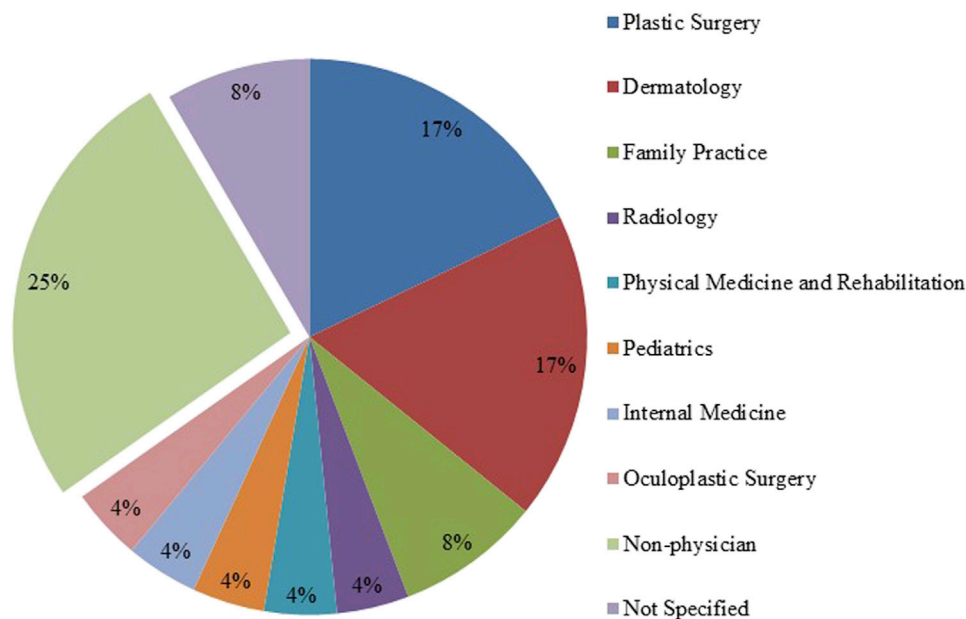


Fig 2. Specialty of dermal filler injectors who underwent litigation. Figure shows the largest proportion of litigated cases were performed by nonphysicians. Most commonly litigated physician subspecialties were plastic surgery and dermatology.

Our search terms were “dermal filler,” “cosmetic injection,” “Zyderm,” “Zyplast,” “Cosmoderm,” “Cosmoplast,” “Restylane,” “Perlane,” “Hylaform,” “Belotero,” “Juvederm,” “Prevelle,” “Artefill,” “Sculptra,” “Radiesse,” “Softform,” “Autologous fat,” “Fascian,” “Eleveess,” “Evolence,” “plastic surgeon,” “dermatologist,” “physician,” “nonphysician,” “nurse practitioner,” and “physician assistant.” Any litigation or professional disciplinary action that did not involve soft-tissue fillers was excluded; the first case discovered was in 1995 and the last in 2013.

The total number of cases and disciplinary actions definitely underreports the true incidence of legal events as the search fails to detect cases (malpractice and otherwise) that did not involve an appeal, were settled, or were decided at the trial level and did not involve a novel legal issue. Malpractice cases are included but this database is not a comprehensive source.

A total of 24 legal documents were identified: 19 cases and 5 disciplinary actions. Of the 19 cases, physicians were named as defendants in 13 (Fig 1). Six of the 7 cases that named a nonphysician as a defendant involved a substance being injected different than the reported filler. Overall, 50% of legal actions from soft-tissue fillers were related to a nonphysician performing the procedure. Of physician subspecialists, dermatologists and plastic surgeons had the highest proportion of litigation (17% each) (Fig 2); this is likely due to these specialties performing a higher volume of the relevant procedures.³⁻⁵ The majority of disciplinary actions were

reprimanding physicians for not being present while a nonphysician employee injected patients with soft-tissue fillers. In 3 of the 5 reprimands, physicians were functioning as medical directors of medical spas.

The most common injury stimulating litigation was granuloma formation or other autoimmune reaction. In our review, Zyderm was the soft-tissue filler most commonly associated with litigation; however, Zyderm was the first soft-tissue filler approved and temporal bias likely explains the higher number of associated cases.

The medico-legal culture is one where physicians are responsible for their physician extenders. Further research should evaluate whether the presence of a physician affects rate of developing complications.

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Funding sources: None.

Conflicts of interest: None declared.

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<http://dx.doi.org/10.1016/j.jaad.2015.06.051>